



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,467	02/06/2004	Edwin Southern	2004-0200	1112
	7590 02/28/200 I, LIND & PONACK, I	EXAMINER		
2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			SKIBINSKY, ANNA	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		02/28/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
•	10/772,467	SOUTHERN, EDWIN				
Office Action Summary	Examiner	Art Unit				
	Anna Skibinsky	1631				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
<ol> <li>Responsive to communication(s) filed on <u>24 November 2006</u>.</li> <li>This action is FINAL. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>						
Disposition of Claims						
4) Claim(s) 17-51 and 55-85 is/are pending in the application. 4a) Of the above claim(s) 28-36,42-45 and 64-85 is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 17-27,37-41,46-51 and 55-63 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 10/25/06;12/20/05;12/08/05.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate				

### **DETAILED ACTION**

### Claim Election/Restriction

#### Election without Traverse

- 1. Applicant's election of Group I (claims 17-27. 37-41, and 46-51) in the reply filed on 11/21/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 28-36, 42-45, and 64-85 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/24/2006.

# **Double Patenting**

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

Art Unit: 1631

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 17-27, 37-41, 46-51 and 55-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 19, 21, 23, 26, 28-30 of copending Application No. 09/422,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have only minor differences encompassed by the instant generic claims. Regarding the limitation of claims 17 and 18 or microporous glass, the species is disclosed on page 11 of the copending application.

Art Unit: 1631

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 37-41, 46-51 and 55-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-24, 26, 27, 29, 30, 38-39 of copending Application No. 09/422804. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have only minor differences encompassed by the instant, generic claims. Regarding the limitation of claims 17 and 18 or microporous glass, the species is disclosed on page 10 of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 17-27, 37-41, 46-51 and 55-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-26, 28-32, 49-52 and 59-60 of copending Application No. 10/115077. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have only minor differences encompassed by the instant generic claims. Regarding the limitation of claims 17 and 18 or microporous glass, the species is disclosed on page 11 of the copending application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1631

# Claim Rejections - 35 USC § 112

Page 5

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 8. Claims 17-27, 37-41, 46-51 and 55-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. The instant claims recite "oligonucleotides with predetermined sequences" which is unclear because it is ambiguous what the oligonucleotides are predetermined with respect to. For the purpose of examination, "predetermined sequences" will be interpreted as sequences with known characteristics or coming from a known source such as certain cell line or method of extracting the sequences.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 1. Claims 37, 39, 40, 46, 55, 57, 58, 61, 48, 69 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Stavrianopoulos et al. (P/N 4,994,373).

Application/Control Number: 10/772,467 Page 6

Art Unit: 1631

2. The instant claims recite an apparatus comprising an impermeable support segregated into at least two defined cells having oligonucleotides, attached at different known locations, containing predetermined sequences covalently attached thereto, wherein the sequence of oligonucleotides of a first cell is different from the sequence of the oligonucleotides of a second cell.

- 3. Stavrianopoulos et al. teach fixing single and double stranded oligonucleotide sequences to nonporous solid supports made of glass (col. 1, lines25-41; and col. 5, lines 37-57). Glass plates with depressions or wells (i.e. cells) are taught (col. 8, lines 40-48), as in claims 37, 39, 46, 48, 58, and 60. Oligonucleotides or oligonucleotide probe sequences (col. 5, line 58 to col. 6, line 4) are covalently attached to the support after the glass has been treated (col. 8, lines 11-56) and wherein the DNA can hybridize to the plates (col. 12, example 7) which involves the binding with terminal nucleotide, as in claims 37, 40, 61, and 63.
- 4. Regarding the limitations of claims 55 and 57, it is brought to Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See MPEP 2113.
- 5. Stavrianopoulos et al. teaches (col. 1, lines 29-30 and col. 5) an array of oligonucleotides with a substrate that may be plastic or glass and that various (i.e. different) polynucleotide samples may be present in the array (col. 8, lines 40-45).

Application/Control Number: 10/772,467 Page 7

Art Unit: 1631

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 17-27, 37-41, 46-48, and 52-63 rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. as applied to 37, 39, 40, 46, 55, 57, 58, 61, 48, 69 and 63 claims above, and further in view of Matkovich et al. (P/N 4,828,386).
- 9. Stavrianopoulos et al. teach fixing single oand double stranded oligonucleotide sequences to nonporous solid supports made of glass (col. 1, lines25-41; and col. 5, lines 37-57). Glass plates with depressions or wells (i.e. cells) are taught (col. 8, lines 40-48), as in claims 17, 19, 20, 47 and 59. Oligonucleotides or oligonucleotide probe sequences (col. 5, line 58 to col. 6, line 4) are covalently attached to the support after

Art Unit: 1631

the glass has been treated (col. 8, lines 11-56) and wherein the DNA can hybridize to the plates (col. 12, example 7) which involves the binding with terminal nucleotide, as in claim 23, 24 and 62.

- 10. Further, Stavrianopoulous et al. shows use of conventional microtiter plates to contain samples (col. 12, lines 20-24), with examples that show a capacity of 3x10<sup>-12</sup> mmol of oligonucleotide, as required by claim 22.
- 11. Stavrianopoulos et al. teaches in situ techniques (col. 5, lines 41-46) for attaching the nucleotide sequence, as required by claim 25.
- 12. Stavrianopoulos et al. does not teach a microporous material attached to the impermeable surface, as required in claims 17 and 18.
- 13. Matkovich et al. teaches the use of a microporous membrane on top of a support (Abstract; col. 3, lines 2-33) which can be used to bind biologically active substances including nucleic acids (col. 6, lines 32-60).
- 14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus taught by Stravrianopoulous et al. to insert a porous membrane as taught by Matkovich et al. One of ordinary skill in the art would be motivated to use the porous membrane on top of the impermeable surface of Stravrianopoulous et al. because Matkovich et al. teach that a porous surface results in a better binding capacity of biological substances (Matkovich et al., col. 3, lines 13-19). One of ordinary skill in the art would have a reasonable expectation of success of using a porous surface with the impermeable surface of Stravrianopoulous et al., because

Art Unit: 1631

Matkovich et al., col. 3, lines 22-28).

- 15. Further, Stavrianopoulous et al. shows use of conventional microtiter plates to contain samples (col. 12, lines 20-24) but does not show the number of wells to be between 72 and  $1.1 \times 10^{12}$  cells as required by claims 21, 41 and 47.
- 16. Matkovich et al. shows microtiter plates with 96 wells via an 8x12 matrix of wells (col. 1, lines 23-26).
- 17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Stravrianopoulous et al. to use the 96 well microtiter plate of Matkovich et al. for the purpose of analyzing an array of up to 96 samples.
- 18. Regarding the limitations of claims 26, 27, and 56, it is brought to Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See MPEP 2113.
- 19. Stavrianopoulos et al. teaches (col. 1, lines 29-30 and col. 5) an array of oligonucleotides with a substrate that may be plastic or glass and that various (i.e. different) polynucleotide samples may be present in the array (col. 8, lines 40-45).

Application/Control Number: 10/772,467 Page 10

Art Unit: 1631

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REWY YUCEL, PH.D SUPERVISORY PATENT EXAMINER TROUBUGGOOD CENTER 1600